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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/092,591	03/08/2002	Shinji Yamamori	Q68895	1085

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2100 PENNSYLVANIA AVE. NW
WASHINGTON, DC 20037-3213

EXAMINER	
MOSS, KERI A	
ART UNIT	**PAPER NUMBER**
1743	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/06/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/092,591	YAMAMORI ET AL.	
	Examiner	Art Unit	
	Keri A. Moss	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-5,8-10 and 13-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-5,8-10 and 13-28* is/are rejected.

7)☒ Claim(s) *1* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/4/07*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 4, 2007 has been entered.

Claims **1, 3-5, 8-10 and 13-28** are pending.

Response to Amendment

2. Rejection of all claims under 35 U.S.C. 112, 1st paragraph has been withdrawn in light of applicant's arguments.

Claim Objections

3. Claim **1** is objected to because of the following informalities: the word "path" should be inserted after the last word of the claim, "flow." Appropriate correction is required.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims **1, 5, 9-10, 13, and 16-18** are rejected under 35 U.S.C. 102(b) as being anticipated by Yamamori et al. (USP 5,957,127). Yamamori discloses a sensor adapted to measure the concentration or presence/absence of carbon dioxide in respiratory gas from a living body, comprising a light-emitting light element (part 3) operable to emit light, a light-receiving element (Fig. 12, part below 6) adapted to receive the light emitted from the light-receiving element, a support member (part 2) supporting the light-emitting element and the light-receiving element such that they are opposed to each other on a single optical axis, the support member being adapted to be located below the nostrils of a living body (at the esophagus or also parts 1a and 1b may be placed just below the nostrils), a respiratory flow path (either part 2e or 1e) formed in the support member so as to cross over the optical axis and adapted to allow the respiratory gas to pass therethrough when the support member is located below the nostrils of the living body and a first guide member (part 1a or 1b) adapted to introduce the respiratory gas from the nostrils to the respiratory gas flow path. The support member contains an engagement member (Fig. 9) adapted to be engaged with a tubular member for supplying oxygen to the nostrils. A second guide member (part 1 a or 1b) capable of guiding the respiratory gas from a mouth of the living body to the respiratory flow path. The sensor may also comprise an oxygen mask (Fig. 3). The sensor also comprises an airway case (part 1) adapted to be located below the nostrils of the living body and having a pair of openings opposing each other and a pair of transparent thin films (parts 1d and 1c) respectively sealing the openings and a pair of supporting members supporting the light-emitting element and the light-receiving

element such that they are opposed to each other on a single optical axis through the openings (Figs 9, 11 and 12, part 2). The first guide member is removably engaged with the support member (Fig 9). The airway case comprises a pair of openings opposing each other (parts 1d and 1c), a respiratory flow path extending between the openings, a pair of transparent thin films (inherent) respectively and a pair of supporting members (Fig. 12 parts supporting parts 3 and part 6) so as to oppose each other on a single optical axis through the openings.

6. Claims **1, 5, 9, 13-14 and 16-18** are rejected under 35 U.S.C. 102(b) as being anticipated by Fertig et al. (USP 5,095,900). Fertig discloses a sensor adapted to measure the concentration or presence/absence of carbon dioxide in respiratory gas from a living body, comprising a light-emitting light element (Fig. 1 part 16) operable to emit light, a light-receiving element (Fig. 1 part 22) adapted to receive the light emitted from the light-receiving element, a support member (Fig. 1 part 14_ supporting the light-emitting element and the light-receiving element such that they are opposed to each other on a single optical axis, the support member being adapted to be located below the nostrils of a living body, a respiratory flow path (Fig. 1 labeled II) formed in the support member so as to cross over the optical axis and adapted to allow the respiratory gas to pass therethrough when the support member is located below the nostrils of the living body (esophagus) and a first guide member (Fig. 4, part 10) capable of introducing the respiratory gas from the nostrils to the respiratory gas flow path. The support member contains an engagement member (the back end of the open

area of part 12, labeled II) adapted to be engaged with a tubular member for supplying oxygen to the nostrils. A second guide member (Fig. 4 part 9) capable of guiding the respiratory gas from a mouth of the living body to the respiratory flow path. The sensor also comprises an airway case (Fig. 4 part 2) adapted be located below the nostrils of the living body (i.e. at the esophagus) and having a pair of openings opposing each other (Fig. 4 parts 6 and 8) and a pair of transparent thin films (Fig. 4 parts 6 and 8) respectively sealing the openings and a pair of supporting members supporting the light-emitting element and the light-receiving element such that they are opposed to each other on a single optical axis through the openings (Figs 9, 11 and 12, part 2). The first guide member is removably engaged with the support member. The thin films are anti-fogging films (column 3 lines 18-27).

7. Claims **1, 5, 9-10, 13-18, 20-24 and 26** are rejected under 35 U.S.C. 102(b) as being anticipated by O'Neil et al. (USP 5,957,127). O'Neil discloses a sensor adapted to measure the concentration or presence/absence of carbon dioxide in respiratory gas from a living body, comprising a light-emitting light element (Fig. 2 part 11) operable to emit light, a light-receiving element (Fig. 2 part 13) adapted to receive the light emitted from the light-receiving element, a support member (Fig. 2 part 5) supporting the light-emitting element and the light-receiving element such that they are opposed to each other on a single optical axis, the support member being adapted to be located below the nostrils of a living body, a respiratory flow path (Fig. 2 between parts 7 and 9) formed in the support member so as to cross over the optical axis and adapted to allow the respiratory gas to pass therethrough when the support member is located below the

nostrils of the living body and a first guide member (Fig. 1 part 21) adapted to introduce the respiratory gas from the nostrils to the respiratory gas flow path. The support member contains an engagement member (Fig. 2 parts 7 and 9) adapted to be engaged with a tubular member for supplying oxygen to the nostrils. A second guide member (Fig. 1 part 23) capable of guiding the respiratory gas from a mouth of the living body to the respiratory flow path. The sensor also comprises an airway case (Figs 1 and 3, part 4) adapted to be located below the nostrils of the living body and having a pair of openings (parts 17) opposing each other and a pair of transparent thin films (column 5 lines 59-62)) respectively sealing the openings and a pair of supporting members supporting the light-emitting element and the light-receiving element such that they are opposed to each other on a single optical axis through the openings (Figs 9, 11 and 12, part 2). The first guide member is removably engaged with the support member. The airway case comprises a pair of supporting members (parts located at 7 and 9) each of which is adapted to removably engage with one of the light-emitting element and the light-receiving element such that they are supported so as to oppose each other on a single optical axis through the openings (Fig. 2). The thin films are anti-fogging films (column 5 lines 59-62).

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

> invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims **3, 8, 19** are rejected under 35 U.S.C. 103(a) as being unpatentable over any of Yamamori, Fertig or O'Neil in view of Dietz and claim **25** is rejected under 35 U.S.C. 103(a) as being unpatentable over O'Neil in view of Deitz. See Yamamori, Fertig and O'Neil, supra. None of the references discussed supra disclose the use of a mask with ear straps nor a guide member with nasal prongs. Dietz discloses a nasal cannula with prongs used with or without a mouth nose mask (Figs 1 and 2; column 2 lines 32-43) for the purpose of sensing inhalation. The nasal cannula uses ear straps

adapted to be hooked around ears for holding the cannula below the nostrils (Figs. 1 and 2). The advantage of using a nasal cannula for sensing is that a nasal cannula is more efficient in detecting nasal inhalation when breathing occurs through a nose (column 2 lines 32-38). The mouth nose mask makes it possible for the nasal cannula to function when the mask user's upper nasal passageways are blocked and breathing takes place through the mouth (column 2 lines 44-47). An additional advantage of using the mask and nasal cannula in combination is that the mouth nose mask allows fluids being delivered by a nasal cannula to enter the mask and be inhaled orally when upper nasal passageways are blocked and breathing takes place through the mouth (column 2 lines 54-57). It would have been obvious for one of ordinary skill in the art to modify the disclosures of Yamamori, Fertig or O'Neil by adding a nasal cannula with ear straps alone or in combination with a mask to the disclosed sensing device in order to gain the advantages of more efficient detection, of ensuring fluid delivery and detection takes place when a patient's nasal passageways are blocked and to ensure fluid delivery through the mouth when the patient's nasal passageways are blocked.

12. Claims **1, 3-5, 8-10, 13, 15-21, 23-28** are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Toole (USP 6,379,312) in view of Passaro et al (USP 4,423,739). O'Toole discloses an apparatus for sensing carbon dioxide while delivering oxygen to the patient. The device includes nasal tubes as well as oral tubes or oral apertures for receiving a breath sample. The body of the device functions as a mask. The nasal tubes attach to a conventional cannula, which provides oxygen. The

conventional cannula contains ear straps. The nasal tubes for a Y-shape (Figs 2 and 3 – dotted outline within the body 10).

While O'Toole does not teach using the cord for sending signals as an ear strap, it would have been obvious for one of ordinary skill in the art to move the cord from part 26 from near the patient's mouth to strap around the ear in order to avoid getting it in the patient's or doctor's way.

O'Toole teaches using attaching end tidal carbon dioxide gas analyzer to the mask apparatus, but does not teach the specifics of the sensor (column 3 lines 62-66). Passaro teaches an end tidal carbon dioxide gas analyzer. The analyzer contains a light-emitting element (Fig. 1 part 11), a light-receiving element (Fig. 1 part 21), a support member supporting the light-emitting element (Fig. 1 parts 13 and 15) and the light receiving element (Fig. 1 part 20), an airway case (part 17) with a respiratory flow path (parts 25 and 27) and a pair of transparent thin films sealing the openings (windows 29). Passaro teaches that the discloses sensor, including the apparatus parameters, provides accurate measurement of carbon dioxide and has an additional advantage of detecting the presence of nitrous oxide and is particularly useful in measurement of exhaled breath of a patient under anesthesia (column 1 lines 36-52). Therefore, it would have been obvious to one of ordinary skill in the art to combine the mask device for delivering oxygen and capturing exhaled breath with the carbon dioxide analyzer disclosed by Passaro in order to gain the advantages of detecting the presence of nitrous oxide and gaining the ability to use the device on anesthetized patients.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keri A. Moss whose telephone number is 571-272-8267. The examiner can normally be reached on 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571)272-1700. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KAM 3/19/07

Keri A. Moss
Examiner
Art Unit 1743

BRIAN R. GORDON
PRIMARY EXAMINER